

REMARKS

Claims 7-11 and 18-26 are currently pending in the present application. Claims 7, 8, 10, 11, 19, 23, and 26 have been amended. Claims 37-31 are withdrawn from consideration. Claims 1-6 and 12-17 were previously withdrawn from consideration.

Applicant has carefully studied the outstanding Office Action. The present response is intended to be fully responsive to all points of rejection and/or objection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application are respectfully requested. No new matter has been added by the amendments, if any, to the specification. Applicant respectfully requests withdrawal of the Examiner's rejections in view of the foregoing amendments and following remarks.

ELECTION/RESTRICTIONS

The Examiner has objected to newly submitted claims 27-31. Specifically, the Examiner has stated:

Newly submitted Claims 27-31 are directed to an invention that is independent or distinct from the invention originally Claimed for the following reasons: The newly presented method claims do not require the particulars of the claimed apparatus, indicating that the claimed method may be performed with a materially different apparatus.

Since applicant has received an action on the merits for the originally presented invention this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly claims 27-31 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03,

Applicant respectfully traverses this election requirement as improper, but provisionally withdraws claims 27-31 without prejudice. Unlike claims 27-31, all previously submitted claims were apparatus claims. Applicant believes that an examination of all of the claims would not impose an undue burden on the Examiner. Applicant therefore respectfully requests reconsideration and withdrawal of the election requirement.

SPECIFICATION

The Examiner has also objected to the introduction of new matter into the disclosure. Specifically, the Examiner has stated:

The amendment filed 6 July 2006 is objected to under 35 U.S.C. 132(a) because it introduces new

matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: a mechanical flow indicator that indicates direction of fluid flow within the valve, as claimed in newly presented claim 19.

Applicant is required to cancel the new matter in the reply to this Office Action.

Applicant respectfully traverses this objection and would direct Examiner's attention to page 7, lines 9-13, wherein the specification discloses the following:

Valve 116 also preferably offers a visual cue to when it performs these functions. Examples of possible visual cues include but are not limited to: transparency in the valve so that fluid flow can be detected; an electronic detector which monitors flow through the valve and provides an indication such as a display or light; or a *mechanical indicator* such as a button which pops out when the valve is activated for these functions, for example.

While the preceding section does not explicitly state that the mechanical device indicates the direction of flow within the body, it may be reasonably inferred. The specification notes that valve 116 performs three primary functions: (1) retroflow protection, which allows flow from patient 102 to the vent pump 108, but prevents flow in the opposite direction; (2) negative pressure relief, which allows fluid from the venous reservoir 112 toward vent pump 108 in the event excess negative pressure builds up in line 118; and positive pressure relief, which provides positive pressure relief from line 118 in the event of a buildup of positive pressure by allowing flow of fluid from the vent pump 108 towards the venous reservoir 112 (or a another appropriate reservoir). Nonetheless, Claim 19 has been amended to more fully describe the parameters of the invention. Applicant respectfully requests reconsideration and withdrawal of Examiner's objection to the specification.

CLAIM REJECTIONS – 35 U.S.C. § 112

Claim 19

The Examiner has rejected claim 19 under 35 U.S.C. § 112, first paragraph, failing to comply with the written description requirement. In particular, the Examiner stated:

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant attempts to claim a mechanical flow indicator that indicates direction of fluid flow within the valve. However, applicant's disclosure with regard to the indicator, found at paragraph 0024 of US 2004/0111058A1, discloses only a mechanical pop-up button that is not disclosed as having any means for indicating the direction of fluid flow through the valve. Accordingly, applicant has not sufficiently described the limitations of the claim.

Claim 19 has been amended to more fully describe the parameters of the invention. Applicant respectfully requests reconsideration and withdrawal of Examiner's objection to the specification.

CLAIM REJECTIONS – 35 U.S.C. § 102

Claim 7, 8, 9-11, 23, and 25

The Examiner has rejected claims 7, 8, 9-11, 23, and 25 under 35 U.S.C. § 102, as being anticipated by U.S. Patent No. 5,697,904 issued to Raines et al. Specifically, the Examiner has stated:

In the specification and figures, Raines [904] discloses the apparatus as claimed by applicant. Specifically, Raines [904] discloses a valve for a medical fluid device comprising first and second inlet ports 91 and 93, and outlet port 92 wherein the two inlet ports are arranged at an acute angle from one another (see column 15, lines 10-54, FIG 15). The inlet ports feature pressure-activated check valves that allow fluid flow in the direction of the outlet, preventing reverse fluid flow.

With regard to applicant's claim limitations drawn to the operation of the claimed valve (allowing fluid to pass in particular directions, relieving pressure, adjusting opening pressures), such limitations are held to be recitations of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114.

Claim 7, 8, 10 and 11 have been amended. It is the Applicant's position that Raines et al. '904 fails to teach each and every limitation of the claimed invention. Specifically, Raines et al. '904 fails to teach any inlet having a two-way valve which is responsive to both negative and positive pressure levels in preventing fluid from passing from the valve back to the patient. In contrast, the multi-port infusion device disclosed in Raines et al. '904 is specifically designed to control the flow of intravenous fluid from a source bag into the patient. Raines et al. '904 is simply a multi-port manifold which allows additional medications to be injected into an intravenous stream prior to entering the catheterized vein of the patient . (see Raines et al. '904, column 8, lines 41-51).

It is well-settled that the “features of an apparatus may be recited either structurally or functionally.” *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). Here, Raines et al. '904 fails to teach an inlet having a two-way valve that both “allows fluid to pass from a source into the valve toward the outlet in the event that negative pressure in the line reaches a predetermined level of negative pressure” and “allows fluid to pass from the

outlet into the valve towards said source in the event that positive pressure in the line reaches a predetermined level of positive pressure.”

This is distinguished from “intended use” where a claim recitation simply states the use of the apparatus. Here, the functional language imposes particular structural requirements on the apparatus, all of which are fully supported by the specification. Specifically speaking, in the Applicant’s claimed invention, the two-way valve allows fluid to pass through the second inlet when pressure in the line of an extracorporeal circuit during heart surgery reaches a predetermined negative level AND allows fluid to pass from the outlet into the valve towards said source when a positive pressure in the line reaches a predetermined level of positive pressure. Raines et al. '904 fails to disclose a structure that anticipates the claimed behavior.

The Examiner has not identified any figure or written description within the specification of Raines et al. '904 that suggests restricting fluid flow in any manner, much less so as to only allow fluid flow through the second inlet into the valve when the line experiences negative pressure (nor out of the second inlet from the valve when the line experiences positive pressure as recited in dependent claim 10).

For these reasons, absent any further suggestion within the specification of Raines et al. '904 that can be specifically identified by the Examiner, the Applicant strongly believes Raines et al. '904 fails to anticipate the present invention, specifically claim 7.

Claims 8, 9-11

With respect to claim 8, the claim provides the following limitation “wherein the two-way valve in the second inlet relieves negative and positive pressure in the line without introducing air into the line.” This limitation is an example of reciting a claim limitation in terms of function. This is distinct from “intended use.” The aforementioned claim limitation requires that the two-way valve in the second inlet allow fluid flow into the valve when negative pressure (at a certain level) is present in the line AND the valve must not allow air to enter the line. There is no suggestion within Raines et al. '904 that the second inlet 93 has any such properties nor does Raines et al. '904 teach any structure that accomplishes the recited function. Meanwhile, the Applicant’s specification clearly suggests structural embodiments that would provide the recited limitations. Therefore, not only is claim 8 not a recitation of “intended use,” but Raines et al. '904 fails to teach a structural limitation that anticipates the limitation of claim 8.

With respect to claim 10, the applicant claims “wherein the two-way valve in the second inlet allows fluid to pass from the line to the source in the event that positive pressure in the line reaches a predetermined level of positive pressure.” Raines et al. '904 fails to disclose any structure that achieves the same function as that in the present invention. In fact, Raines et al. '904 fails to disclose any sort of regulation on the second inlet that would control the flow of fluid.

Finally, with respect to claims 11 and 23, there is no structure within Raines et al. '904 that regulates the flow of fluid through the two-way valve in the second inlet based on the level of positive pressure within the line. As an extension of that argument, Raines et al. '904 cannot teach that the predetermined levels of pressure necessary to activate the two-way valve can be adjusted. For this reason, claims 11 and 23 are in condition for allowance.

It is respectfully requested, that claim 8, 9-11, 23, and 25 are in condition for allowance in their present forms. The Examiner has not identified any structural limitations within Raines et al. '904 that anticipates the limitations of claims 8, 9-11, 23, and 25 so any further rejections directed toward those claims limitations cannot be made final.

CLAIM REJECTIONS – 35 U.S.C. §103(a)

Claims 9, 18

The Examiner has rejected claims 9 and 18 under 35 U.S.C. §103(a), as being unpatentable over Raines et al. (U.S. Patent No. 5,697,904) in view of Webster (U.S. Patent No. 4,304,257). The Examiner has stated that:

In the specification and figures, Raines [904] discloses the device substantially as claimed by applicant with the exception of a visual indicator of fluid flow in the valve. Webster [257] discloses a medical fluid valve that comprises a transparent face plate 120 that allows an operator to visually assess blood flowing through the valve (see column 4, lines 42-60). Therefore, it would have been obvious to provide the valve disclosed by Raines [904] with a transparent portion as disclosed by Webster [257] in order to allow an operator to visually assess the flow of blood through the valve, as taught by Webster [257].

This rejection is respectfully traversed. Claims 9 and 18 depend from independent claim 7. For the reasons previously mentioned, claims 9 and 18 are non-obviousness despite the teachings of Raines et al. '904 in view of Webster '257. The prior art cited by Examiner does not, either alone or in combination, teach or disclose every element of Applicant's invention.

Claim 19

The Examiner has rejected claim 19 under 35 U.S.C. §103(a), as being unpatentable over Raines et al. (U.S. Patent No. 5,697,904) in view of Priem (U.S. Patent No. 4,838,338). The Examiner has stated that:

In the specification and figures, Raines [904] discloses the device substantially as claimed by applicant with the exception of a mechanical indicator of fluid flow in the valve. Priem [338] discloses a fluid flow device that comprises a valve and a flow indicator comprising a mechanical flapper that provides the operator with a visual indication that fluid is flowing through the valve (see column 5, lines 37-50)

With regard to applicant's recitation drawn to the operation of the indicator to indicate a direction of flow through the device, such a limitation is a statement of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP § 2114. In the instant case, the Priem [338] device is capable of flapping in opposite directions to indicate the direction of flow in the device, meeting the limitations of the claims.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add the mechanical flapper disclosed by Priem [338] to the fluid flow valve disclosed by Raines in order to provide the operator visual indication of fluid flowing through the valve, as taught by Priem [338].

This rejection is respectfully traversed. Claim 19 depends from claim 9, which in turn depends from independent claim 7. For the reasons previously mentioned, claim 19 is non-obviousness despite the teachings of Raines et al. '904 in view of Priem '338. The prior art cited by Examiner does not, either alone or in combination, teach or disclose every element of Applicant's invention.

Claims 20, 21

The Examiner has rejected claims 20 and 21 under 35 U.S.C. §103(a), as being unpatentable over Raines et al. (U.S. Patent No. 5,697,904) in view of Sassano (U.S. Patent No. 4,747,826). The Examiner has stated that:

In the specification and figures, Raines [904] discloses the device substantially as claimed by applicant with the exception of an electronic flow detector connected to a visual display. Sassano [826] discloses a fluid flow system for rapid venous infusion that comprises tubing, valves, and means for sensing fluid flow. The device comprises fluid flow controllers 38 (which may include valves) and monitors coupled to infusion pump 14 (see column 4, lines 14-26). The flow sensors are electronic in nature and have a corresponding visual display (see column 6, lines 23-30). The system, including its sensors and controllers, allow for rapid, automated infusion to a patient that can be monitored by an operator consulting the display (see column 2, lines 16-40). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to couple an electronic fluid sensor with visual display, as disclosed by Sassano [826], with the valve disclosed by Raines in order to provide for easy fluid flow monitoring by a single operator, as taught by Sassano [826].

This rejection is respectfully traversed. Claims 20 and 21 depends from claim 9, which in turn depends from independent claim 7. For the reasons previously mentioned, claims 20 and 21 are non-obviousness despite the teachings of Raines et al. '904 in view of Sassano '826. The prior art cited by Examiner does not, either alone or in combination, teach or disclose every element of Applicant's invention.

Claims 22, 26

The Examiner has rejected claims 22 and 26 under 35 U.S.C. §103(a), as being unpatentable over Siposs et al. (U.S. Patent No. 4,758,224) in view of Raines et al. (U.S. Patent No. 5,697,904). The Examiner has stated that:

In the specification and figures, Siposs [224] discloses the device substantially as claimed by applicant. With regard to claim 26, Siposs [224] discloses a suction control valve with first inlet 42, a second inlet 32, and an outlet 20. The first inlet is regulated by a duckbill valve 44 that allows only one-way fluid flow. The second inlet allows fluid (such as atmospheric gas) to pass from a source (the atmosphere) in the valve towards the outlet in the event the vacuum in outlet 20 goes too far below atmospheric pressure (see FIG 1, column 3, lines 5-67).

With regard to claim 22, Siposs [224] further discloses relief passages 28, 30, that act as expelling outlets that permit fluid flow to open air (see column 4, lines 48-57).

Siposs [224] fails to disclose that the first and second inlet have an axis of less than 90 degrees between them. However, Raines [904] discloses a two-inlet valve with the inlets disposed at an acute angle from one another (see FIG 1 5). It would have been an obvious matter of design choice to form the inlets disclosed by Siposs [224] in the acute angle shape disclosed by Raines [904], since such a modification would have involved a mere change in the form or shape of a component. A change in form or shape is generally recognized as being within the level of ordinary skill in the art. See MPEP 2144.04 (IV)(B)

This rejection is respectfully traversed. Claims 22 and 26 depends from independent claim 7. For the reasons previously mentioned, claims 22 and 26 are non-obviousness despite the teachings of Siposs et al. '224 in view of Raines et al. '904. The prior art cited by Examiner does not, either alone or in combination, teach or disclose every element of Applicant's invention.

Claim 24

The Examiner has rejected claim 24 under 35 U.S.C. §103(a), as being unpatentable over Siposs et al. (U.S. Patent No. 4,758,224), in view of Hogendijk et al. (U.S. Patent No. 7,033,336), in view of Raines et al. (U.S. Patent No. 5,697,904). The Examiner has stated that:

In the specification and figures, Siposs [224] discloses the device substantially as claimed by applicant (see rejection above) with the exception of providing a venous reservoir as the source of fluid for the second inlet passage. With regard to claim 22, Hogendijk [336] discloses a catheter

assembly with a first inlet 258 and a second inlet 224, and an outlet passage 213 wherein the second inlet is coupled to a venous return line (see column 7, lines 45-67, column 8 lines 1-8, FIG 60). The second inlet is regulated by a valve 256 that opens if the negative pressure in outlet line 213 is too great, allowing for pressure relief such that high levels of suction related aspiration will not harm the patient's vessel (see column 3, lines 45-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a venous reservoir or source as disclosed by Hogendijk [336] to the valve apparatus disclosed by Siposs [224] in order to prevent suction-related harm to the patient's vessel, as taught by Hogendijk [336].

Siposs [224] and Hogendijk [336] fail to disclose that the first and second inlet have an axis of less than 90 degrees between them. However, Raines [904] discloses a two-inlet valve with the inlets disposed at an acute angle from one another (see FIG 15). It would have been an obvious matter of design choice to form the inlets disclosed by Siposs [224] and Hogendijk [336] in the acute angle shape disclosed by Raines [904], since such a modification would have involved a mere change in the form or shape of a component. A change in form or shape is generally recognized as being within the level of ordinary skill in the art. See MPEP 2144,04 (IV)(B).

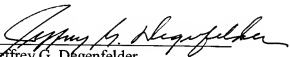
This rejection is respectfully traversed. Claim 24 depends from independent claim 7. For the reasons previously mentioned, claim 24 is non-obviousness despite the teachings of Siposs et al. '224 in view of Hogendijk et al. '336, in view of Raines et al. '904. The prior art cited by Examiner does not, either alone or in combination, teach or disclose every element of Applicant's invention.

CONCLUSION

Applicant has fully responded to the Examiner's rejections. It is respectfully urged that the subject application is patentable over references cited by Examiner and is now in condition for allowance. Applicant requests consideration of the application and allowance of the claims. If there are any outstanding issues that the Examiner feels may be resolved by way of a telephone conference, the Examiner is cordially invited to contact Jeffrey G. Degenfelder at 972.367.2001.

The Commissioner is hereby authorized to charge any additional payments that may be due for additional claims to Deposit Account 50-0392.

Respectfully submitted,

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